K122163

510(k) Summary

OCT 31 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, M.D. Chief Medical Officer
Initial Date Prepared:	7/19/2012

DEVICE NAME

Trade/Proprietary Name:	Certex™ Spinal Implant System
Common Name:	Spinal Implants
Device Class:	Class II
Classification Name:	MNI §888.3070 – Orthosis, Spinal Pedicle Fixation KWP §888.3050 – Appliance, Fixation, Spinal Interlaminal

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The intended use of the Certex Spinal Implant System is to promote fusion of the subaxial cervical spine and cervico-thoracic junction (C3 – T3 inclusive). The indications for use are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal Stenosis,
- Failed previous fusion,
- Revision of previous cervical spine surgery,
- Spinal tumors.

The use of screws is limited to placement in TI-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

DEVICE DESCRIPTION

The Certex Spinal Implant System consists of screws, hooks, rods, and cross connectors. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patient anatomy. The Certex Spinal Implant System is manufactured from Titanium alloy in accordance with ASTM F136 and will be provided non-sterile. All implants are intended for single use only and should not be reused under any circumstances.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Certex Spinal Implant System is substantially equivalent to predicate devices based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

PREDICATE DEVICES

- Aesculap, Inc. S4 Spinal System (K050979)
- Seaspine, Inc. Sierra System (K062934)
- X-spine Fortex Spinal Fixation System (K090224)

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F1717 – *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

- Static Compression Bending
- Static Torsion
- Dynamic Compression Bending

In conclusion, biomechanical testing results indicate that the Certex Spinal Implant System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

X-Spine Systems, Incorporated
% Mr. David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

OCT 31 2012

Re: K122163
Trade/Device Name: Certex™ Spinal Implant System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: September 28, 2012
Received: October 01, 2012

Dear Mr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122163

Indications for Use

510(k) Number (if known): K122163

Device Name: Certex™ Spinal Implant System

Indications for Use:

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Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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